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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL –6902-01
March 20, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gene Abels
Chief Executive Officer
Medical Associates of Gallipolis, Inc.
936 State Route 160
Gallipolis, OH 45631

Facility I.D.#: 123042

Dear Mr. Abels:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on March 7, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

Quality Standards –Personnel – *Interpreting Physicians* 21 CFR 900.12(a)(1)(i)-(iii) & (a)(4)

Your staff failed to show documents verifying that the following interpreting physicians meet the initial requirement of being certified in mammography by an FDA approved certifying body or having two months of initial training in the interpretation of mammograms prior to April 28, 1999. The interpreting physicians are [redacted] and [redacted]

Quality Standards –Personnel –*Radiologic Technologists* 21 CFR 900.12(a)(2)(i)(B) & (a)(4)

Your staff failed to show documents verifying that the following radiologic technologists meet the initial requirement of holding either a valid state license or a valid certificate from an FDA approved body. The radiologic technologists are: [redacted] **and** [redacted]

Quality Standards –Personnel – *Medical Physicists* 21 CFR 900.12(a)(3)(i)&(ii) & (a)(4)

Your staff failed to show documents verifying that the medical physicist, [redacted] meets the initial requirement of holding either a valid state license or approval letter or having a valid certificate from an FDA approved body.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, these represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. Quality Assurance – Equipment - 21 CFR 900.12(e)(2)(iii)

The inspection phantom image score using the FDA mammography phantom revealed 2 speck groups. The minimum phantom image speck group score required for acceptance before any further mammography examination is 3.

2. Quality Assurance – Equipment - 21 CFR 900.12(e)(8)(i)&(ii) as further required in 21 CFR 900.12(e)(1)

Your records revealed that your facility failed to document corrective actions for processor quality control failures.

3. Quality Assurance – Equipment - 21 CFR 900.12(e)(8)(i)&(ii) as further required in 21 CFR 900.12 (e)(2)

Your records revealed that your facility failed to document corrective actions before further mammography examinations, for failing image score, or a phantom background optical density or density difference found outside the regulatory limits.

4. Quality Standards –Personnel – *Interpreting Physicians* 21 CFR 900.12(a)(1)(iii)(B) & (a)(4)

Your staff failed to show documents verifying that the following interpreting physicians meet the initial experience requirement of having interpreted or multi-read 240 mammograms in six months. The interpreting physicians are: [redacted] and [redacted]

5. Quality Standards –Personnel – *Interpreting Physicians* 21 CFR 900.12(a)(1)(i)-(iii) & (a)(4)

Your staff failed to show documents verifying that the following interpreting physicians meet the initial requirement of having 40 hours of medical education in mammography prior to April 28, 1999. The interpreting physicians are: [redacted] and [redacted]

6. Quality Standards –Personnel –*Radiologic Technologists* 21 CFR 900.12(a)(2)(ii) & (a)(4)

Your staff failed to show documents verifying that the radiologic technologist, [redacted] meets the initial requirement of having 40 contact hours of training specific to mammography.

7. Quality Assurance – *Mammography Medical Outcomes Audit* 21 CFR 900.12(f)(3)

Your staff failed to designate a reviewing interpreting physician for the purpose of evaluating your facility medical outcome audit to follow-up positive mammography cases.

Level 3 *Repeat* Finding:

Retention of Personnel Records - 21 CFR 900.12 (a)(4)

During the inspection at your facility and upon request by the inspector, your staff was unable to provide several required personnel qualification documentation for review by the inspector.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received. The problem is identified as **repeat Level 3** because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement **permanent correction** of the problem found during your previous inspection on February 25, 2000.

The inspector also evaluated your facility medical physicist survey report dated June 5, 2000. The survey report indicated "pass" notations for all of the technologist's quality control program. Whereas at the time of the inspection, the inspector found in the quality control records covering the time period preceding and after the June 5, 2000 medical survey that there were failures in some quality program areas. This is noted in the Inspector Remarks portion of your facility, February 27, 2001 Post Inspection Report.

The other item listed in your February 27, 2001 inspection report identified, as Level 3 should also be corrected. We will verify correction of this item during our next inspection. You are not required to address the Level 3 item in your written response.

You must act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please send a copy to the State radiation control office:

Ms. Stacey Melick
Ohio Department of Health
Radiologic Technology Section
P.O. Box 118
Columbus, Ohio 43266-0118

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Mary L Womack for
Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/SMelick

Priscilla F. Butler, M.S.
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